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EXAMINER
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PORTNER, VIRGINIA ALLEN

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1645

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/724,194	<b>Applicant(s)</b> KOKAI-KUN ET AL.	
	<b>Examiner</b> GINNY PORTNER	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18, 21-25 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 21-25 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Claims 18, 21-25, 28, 39-58 are pending.  
Claims 18, 21-25 and 28 are under consideration.  
Claims 39-58 remain withdrawn from consideration.

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 17, 2007 has been entered.

### ***Objection to the Specification Withdrawn***

1. The disclosure objected to because it contains an embedded hyperlink and/or other form of browser-executable code, has been obviated in light of the fact that Applicant deleted the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. see page 71, citation 27.

### ***Objections/Rejections Maintained/ Response to Arguments***

2. Applicant's arguments filed December 17, 2007 have been fully considered but they are not persuasive.
3. ***Claim Rejections - 35 USC § 103*** Claims 18, 21-25 and 28 under 35 U.S.C. 103(a) as being unpatentable over Fischer et al (US Pat. 6,939,543, filing date June 2001) in view of Patti (US Pat. 6,703,025, filing date August 31, 1999) is traversed on the grounds that:

Art Unit: 1645

4. Fischer et al fail to teach monoclonal antibodies that bind specifically to ribitol phosphate wall teichoic acid of *S. aureus*.

5. It is the position of the examiner the abstract also describes the invention of Fischer et al to include :

6. "The present invention encompasses monoclonal and chimeric antibodies that bind to lipoteichoic acid of Gram positive bacteria. The antibodies also bind to whole bacteria and enhance phagocytosis and killing of the bacteria in vitro and enhance protection from lethal infection in vivo. The mouse monoclonal antibody has been humanized and the resulting chimeric antibody provides a previously unknown means to diagnose, prevent and/or treat infections caused by gram positive bacteria bearing lipoteichoic acid. This invention also encompasses a peptide mimic of the lipoteichoic acid epitope binding site defined by the monoclonal antibody. This epitope or epitope peptide mimic identifies other antibodies that may bind to the lipoteichoic acid epitope. Moreover, the epitope or epitope peptide mimic provides a valuable substrate for the generation of vaccines or other therapeutics." That antibodies are specific for Gram positive bacterial lipoteichoic acid.

7.

The "FIELD OF THE INVENTION" describes the invention to include:

"This invention in the fields of immunology and infectious diseases relates to antibodies that are specific for Gram positive bacteria, particularly to lipoteichoic acids exposed on the surface of the bacteria."

At paragraph 10, of the instant Specification, narrative teaches the importance of treating Staphylococcal infection:

a. Staphylococcal infections are difficult to treat for a variety of reasons. Resistance to antibiotics is common and becoming more so. See L. Garrett, *The Coming Plague*, "The Revenge of the Germs or Just Keep Inventing New Drugs" Ch. 13, pgs. 411-456, Farrar, Straus and Giroux, NY, Eds. (1994). In one study, the majority of Staphylococci isolated from blood cultures of septic infants were multiply resistant to antibiotics (A. Fleer et al., *Pediatr. Infect. Dis.* 2:426 (1983)). A more recent study describes methicillin-resistant *S. aureus* (J. Romero-Vivas, et al., *Clin. Infect. Dis.* 21:1417-23 (1995)) and a recent review notes that the emergence of antibiotic resistance among clinical isolates makes treatment difficult (J. Lee., *Trends in Micro.* 4(4):162-66 (April 1996). Recent reports in the popular press also describe troubling incidents of antibiotic resistance. See *The Washington Post* "Microbe in Hospital Infections Show Resistance to Antibiotics," May 29, 1997; *The Washington Times*, "Deadly bacteria outwits antibiotics," May 29, 1997.

At paragraph 12, of the instant Specification, the invention is described as being directed to both coagulase positive (*S. aureus*) and negative (*S. epidermidis*) types of *Staphylococcus*:

Accordingly, there is a need in the art to provide monoclonal antibodies that can bind to *Staphylococcus* of both coagulase types and that can enhance phagocytosis and killing of the bacteria and thereby enhance protection in vivo. There is also a need in the art for the epitope of the site to which such antibodies can bind so that other antibodies with similar abilities can be identified and isolated.

The SUMMARY OF THE INVENTION clearly states that the invention is directed to opsonic and protective monoclonal and chimeric antibodies ... of Gram positive bacteria.

“To address these needs in the art, the present invention encompasses opsonic and protective monoclonal and chimeric antibodies that bind to lipoteichoic acid of Gram positive bacteria. The antibodies also bind to whole bacteria and enhance phagocytosis and killing of the bacteria in vitro and enhance protection from lethal infection in vivo. The mouse monoclonal antibody has been humanized and the resulting chimeric antibody provides a previously unknown means to diagnose, prevent and/or treat infections caused by gram positive bacteria bearing lipoteichoic acids. This invention also encompasses a peptide mimic of the lipoteichoic acid epitope binding site defined by the monoclonal antibody. This epitope or epitope peptide mimic identifies other antibodies that may bind to the lipoteichoic acid epitope. Moreover, the epitope or epitope peptide mimic provides a valuable substrate for the generation of vaccines or other therapeutics.”

8. Therefore the reference describes combination compositions of antibodies for antibody therapy (see col. 11, lines 16-18 and col. 11, lines 32-34), and obtain the combination composition of antibodies by immunization with mixtures of antigens, which would include both types of teichoic acid antigens (see col. 11, lines 41-50).

9. It has long been held that a reference must be evaluated in its entirety, not on the basis of its preferred embodiments or working examples. *In re Mills*, 470 F.2d 649, 651, 176 (USPQ 198 (CCPA 1972)). While a focus of Fischer et al is directed to the production of anti-glycerol teichoic acid antibodies, the reference also describes the production of additional antibodies to additional

Art Unit: 1645

antigens present in *Staphylococcus aureus* lipoteichoic acid. Fischer et al specifically teach the teichoic acids of *Staphylococcus aureus* to comprise ribitol phosphate and glycerol phosphate in the *S.aureus*' teichoic acid (see col. 5, lines 32-35), and Fischer et al states their antibodies are directed to "LTA exposed on the surface of the cell wall of Gram positive bacteria (paragraph 2)" and goes on to state: "Teichoic acids are polymers of either glycerol phosphate or ribitol phosphate with various sugars (paragraph 3) ". Therefore Fischer teaches and suggests combination compositions of antibodies directed to ribitol phosphate and glycerol phosphate antigens.

10. Applicant asserts that Patti et al fail to teach and suggest anti-teichoic antibodies that could be protective and do not teach monoclonal antibodies to ribitol teichoic acid.

11. It is the position of the examiner Patti et al is directed to "Multicomponent vaccines" and while the reference clearly describes proteins for stimulation of antibodies, the reference goes beyond just discussing proteins and describes utilizing teichoic acid epitopes to stimulate antibodies that induce cross reactive antibodies, as well as teaches glycerol and ribitol phosphate induce anti-teichoic antibodies:

12. DOCUMENT-IDENTIFIER: US 6703025 B1 Detailed Description Text (25):  
As used herein, an "antigenically functional equivalent" protein or peptide is one that incorporates an epitope that is immunologically cross-reactive with one or more epitopes either derived from any of the particular MSCRAMM proteins disclosed (e.g., FnB-B, FnB-A, FnBP-B and FnBP-A) or derived from any of the particular bacterial components disclosed (e.g., teichoic acids, alpha toxin and capsular polysaccharide type 5). Antigenically functional equivalents, or epitopic sequences, may be first designed or predicted and then tested, or may simply be directly tested for cross-reactivity.

Detailed Description Text (95):

Teichoic acids, lipoteichoic acid for example, which are polymers of glycerol or ribitol

Art Unit: 1645

phosphate, are linked to the peptidoglycan and can be antigenic. Antiteichoic antibodies detectable by gel diffusion

The Fischer et al reference was cited for teaching the importance of producing productive antibodies directed to gram negative bacteria, to include *Staphylococcus aureus* and *epidermidis*. Fischer et al goes on to teach the production of polyclonal, monoclonal, chimeric, human and humanized antibodies to *S. aureus* teichoic acids and suggests antibodies to glycerol and ribitol phosphate antigens. Patti et al was cited to show that ribitol phosphate is immunogenic, and induces antibodies, wherein polyclonal antibodies to ribitol phosphate have been made. Patti et al teach the production of antibodies to glycerol or ribitol phosphate in an analogous art for the purposes of producing anti-teichoic antibodies (see col. 22, lines 48-52) associated with staphylococcal antigens (abstract) to increase the opsonization and phagocytosis of *S. aureus* (see col. 22, lines 30-35 and 48-52).

13. Fischer et al teach the formulation of anti-LTA antibodies into pharmaceutical compositions that comprise a “therapeutically effective amount of a pharmaceutical composition comprising the anti-LTA immunoglobulin (whether polyclonal or monoclonal or chimeric, including fragments, regions and derivative thereof) and a pharmaceutically acceptable carrier.”

14. Fischer et al in view of Patti et al provide guidance, teaching, suggestion and motivation to make monoclonal, chimeric, humanized and human antibodies to ribitol teichoic acid, a wall component of known human pathogenic strains of *Staphylococcus aureus* because Fischer et al teach antibodies directed to lipoteichoic acids “can block the binding of Gram positive bacteria to epithelial cells, such as human epithelial cells (Fischer et al, first paragraph)” and Patti et al teach ribitol phosphate is immunogenic and induces antibodies directed to *S. aureus* LTA. It is obvious to make a monoclonal antibody to an antigen for which polyclonal antibodies have been

Art Unit: 1645

made. In re Erlich, 1988. Fischer et al in view of Patti et al obviate the instantly claimed invention as now claimed.

*New Grounds of Rejection*

*Claim Rejections - 35 USC § 112*

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 18 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a humanized antibody or a humanized single-chain Fv (scFv), or fragments thereof comprising both VH and VL domains, wherein the humanized antibody, the humanized scFv, and fragments thereof comprise 6 CDRs, three from the VH domain and three from the VL domain, wherein the humanized antibody, the humanized scFv, and fragments thereof bind the same antigen as the parental non-human antibody, does not reasonably provide enablement for a humanized variable domain, a humanized antibody, a humanized scFv, and fragments thereof that do not bind to the same antigen and the whole antibody or bind a different antigen than the parental non-human antibody as broadly encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.



Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 1 12, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,  
“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

Claims 1 and 21-25 and 28 include and are broadly drawn to fragments of the VH or VL domains (see claim 1 “or fragment thereof”), which do not contain a full set of 6 CDRs and does not bind antigen.

Claim 25 includes humanized scFv, fragments which need not bind antigen or bind a different antigen than the parental non-human antibody and are interpreted to retain a/some murine framework residue(s) (i.e., substantially identical to human framework regions). It is noted that claims 21-24 and 28 are also drawn to a monoclonal antibody, but the claim language encompasses humanized antibody fragments, which do not contain the full set of 6 CDRs and would not bind antigen and the claims do not require that the antibody or fragments thereof bind antigen or bind the same antigen as the parental non-human antibody.

The specification discloses only humanized antibodies that contain both a VH and a VL chain and the humanized antibodies bind the same antigen as the parental non-human antibody (anti-LTA) (see Examples and Figures). The specification does not enable humanized variable domains, humanized antibodies, humanized scFvs, and fragments thereof, which do not contain the necessary CDRs that bind the same antigen as the whole antibody.

The claims encompass a humanized antibody, a humanized scFv and fragments thereof, which do not contain a full set of CDRs and do not bind antigen or the same antigen as the parental non-human antibody and can retain a/some murine residue(s) in the framework regions (i.e., substantially identical to human framework regions). It is well established in the art that the formation of an intact antigen-binding site of all antibodies requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs or hypervariable regions, which provide the majority of the contact residues for the binding of the antibody to its target epitope (Paul, *Fundamental Immunology*, 3<sup>rd</sup> Edition, 1993, pp. 292-295, under the heading "Fv Structure and Diversity in Three Dimensions"). The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity, which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites (Paul, page 293, first column, lines 3-8 and line 31 to column 2, line 9 and lines 27-30). Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al (Proc. Natl. Acad. Sci. USA 1982 Vol. 79: page 1979). Rudikoff et al teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. It is unlikely that humanized antibody, humanized scFv and fragments thereof as defined by the claims, which may contain less than the

full complement of CDRs from the heavy and light chain variable regions have the required binding function. Applicants have provided insufficient evidence or nexus that would lead the skilled artisan to predict the ability of producing a humanized antibody, a humanized scFv and fragments thereof containing fewer the needed number of CDRs to bind antigen, resulting in a humanized antibody that retains the antigen specificity of the parental non-human antibody. Further, a fragment of the light and heavy variable and constant domains can be any one of the CDRs, any one of the constant regions (CH1-3) and also may be the hinge region. However, the claim language also reads on small amino acid sequences, which are incomplete regions of the variable and/or constant region of the antibody. One of skill in the art would neither expect nor predict the appropriate functioning of the antibody as broadly as is claimed.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention as it pertains to a method of producing a humanized antibody, a humanized scFv and fragments thereof commensurate with the scope of the claims from the written disclosure alone.

### ***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**16.** Claims 18 and 24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al (US Pat. 4,954,449) in view of Argaman et al (1974).

**17.** Hunter et al disclose compositions of human monoclonal antibodies directed to polyribosyl ribitol phosphate together with a pharmaceutically acceptable carrier (see col. 3, lines 14-19 and lines 29-32), the antibodies being present in the composition in a therapeutically effective amount (see claim 2) and can provide passive prophylaxis (see Hunter et al, col. 6, line 22).

**18.** The monoclonal antibodies in the composition are directed to pathogenic bacteria that comprise poly ribitol phosphate, and in light of evidence provided by Argaman et al shows cross reactivity between H. influenza and Staphylococcus aureus (see Argamon et al, abstract), inherently the compositions of Hunter et al anticipate the instantly claimed invention as now claimed.

**19.** Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art."

### ***Double Patenting***

**20.** The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

Art Unit: 1645

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 18, 21-25 and 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,169,903. Although the conflicting claims are not identical, they are not patentably distinct from each other because

22. The allowed compositions of US Pat. 7,169,903, claims 7-10 include antibodies directed to peptidoglycan and lipoteichoic acid that include monoclonal antibodies directed to N-acetylglucosamine and teichoic acids see described embodiments at “ [0003] Man has long battled infections caused by bacteria, particularly Gram-positive positive bacteria. The surface structures and cell wall of Gram-positive bacteria form a complex matrix that performs functions essential in bacteria and host interactions. The cell wall consists of a peptidoglycan macromolecule (repeating units of N-acetylglucosamine and N-acetylmuramic acid) and attached accessory molecules including teichoic acids, lipoteichoic acids, and carbohydrates (see, e.g., (9) and (24)). In addition, there are many surface proteins anchored to the bacterial cell wall (see, e.g., (17))” which are encompassed by

23. the instant claims are directed to compositions of monoclonal antibodies directed to teichoic acids plus additional carbohydrates and proteins depending on the species and include monoclonal antibodies directed to **GlcNAc** (N-acetylglucosamine ) modification and cross react with WTA from other staphylococcal species “[0041] The term "wall teichoic acid" (WTA), as used herein, includes complex surface-exposed polymers covalently linked to the peptidoglycan in staphylococcal cell walls. WTA also includes soluble whole WTA or fragments thereof. In one embodiment, WTA may be produced synthetically. In another embodiment, WTA may be isolated from staphylococci such as, but not limited to, *S. aureus*. In another embodiment, WTA may be isolated from a non-staphylococcal organism such as, but not limited to, *L. monocytogenes*. A WTA preparation is comprised of soluble whole WTA or fragments thereof. [0065] The present invention provides antibodies, including monoclonal antibodies, and chimeric, humanized and fully human antibodies, fragments, derivatives, and regions thereof, which bind to WTA of Gram positive staphylococci. In one embodiment, the antibodies of the invention bind to the patient ligand that staphylococcal WTA binds to. These anti-ligand antibodies may, for example, inhibit the binding of staphylococci to patient surfaces by inhibiting the interaction of WTA with its ligand. Gram positive bacteria, unlike Gram negative bacteria, take up the Gram stain as a result of a difference in the structure of the cell wall. The cell walls of Gram negative bacteria are made up of a unique outer membrane of two opposing phospholipid-protein leaflets, with an ordinary phospholipid in the inner leaflet but the extremely toxic lipopolysaccharide in the outer leaflet. The cell walls of Gram positive bacteria seem much simpler in comparison, containing two major components, peptidoglycan and teichoic acids plus additional carbohydrates and proteins depending on the species. Though the structure of WTA

differs between different staphylococcal species, antibodies raised against *S. aureus* WTA may recognize some common **WTA modifications such as D-Alanine esters or GlcNAc**” (N-acetylglucosamine ) modification and cross react with WTA from other staphylococcal species. Moreover anti-WTA antibodies may also specifically bind non-staphylococcal species. For example, *Listeria monocytogenes* has the same WTA structure as *S. aureus*. Thus, antibodies that specifically bind *S. aureus* WTA may also specifically bind *L. monocytogenes*.

Though the scope of the allowed claims is not identical to the instant claims, the allowed claims are directed to a genus of compositions that comprise antibodies of the instant claims, the instant claimed being a species of invention encompassed by the allowed genus.

### ***Conclusion***

24. This is a non-final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/  
Examiner, Art Unit 1645  
March 29, 2008

/Mark Navarro/  
Primary Examiner, Art Unit 1645